

Appl. No. 09/834,434

Docket No. 3123-4006REMARKS/ARGUMENTSStatus of Claims

Claims 1-58 are pending in this application. Claims 6-8 and 13-48 have been withdrawn. Claims 6-8 and 13-48, which were previously withdrawn subject to a restriction requirement, are cancelled herein and will be pursued in a divisional application. Claims 51-53 have been cancelled without prejudice and will be pursued in a continuation application. Claims 1-5, 9-12 and 49-54 stand rejected.

Claims 49-50 are amended herein. Claims 55-58 are newly added herein. No new matter is introduced by the amendments and newly added claims.

Interview Summary

Applicants would like to thank the Examiner for the courtesy extended to the undersigned during the March 15 and March 16, 2006 telephonic interviews. During the interview of March 15, support for step (d) of claim 1, requiring "transferring the separated transferable reproductive elements to secondary cultures," was discussed. Applicants pointed out that Section J of the Examples, titled "Transfer Of Fungal Growth Units," (pp. 56-57) fully supports the subject matter of step (d). In particular, section J describes the inoculation of microtiter plate wells with spores (i.e., "transferable reproductive elements") from "plate-grown colonies." Moreover, the transfer is effected by using, for example, toothpicks, pins, pin tools or by "pipetting small aliquots of suspensions of spores, protoplast or hyphal elements." The Examiner on March 16 expressed agreement that step (d) of claim 1 is supported by the example. Accordingly, the Examiner indicated that claim 1 as well as claims 2-5, 9-12 and 54 were in condition for allowance.

The Examiner also agreed that claims sub-generic to claim 1 could be added to the application. Accordingly, Applicants present herein new claims 55-58 which recite the genera *Aspergillus*, *Fusarium*, *Chrysosporium*, and *Trichoderma*, respectively. On May 3, 2006 and May 9, 2006, telephone interviews were held with the Examiner during which time the Examiner advised that claims 1-5, 9-12, 54 and new claims 55-58 were in condition for allowance. Claims 49-50, which were rejected under 35 U.S.C. § 112, first paragraph, for lack

Appl. No. 09/834,434

Docket No. 3123-4006

of written description were to be allowable upon the deletion of the phrase "and descendants thereof." Accordingly, those claims have been amended herein to delete that phrase. In addition, claims 51-53 are cancelled herein in view of the continued rejections under 35 U.S.C. § 112.

The deletion of the phrase "and descendants thereof" and the cancellation of claims 51-53 are made solely to expedite allowance of the generic claims and claims 49-50, directed to currently preferred embodiments. It will be noted that the deletion of the phrase "and descendants thereof" and cancellation of claims 51-53 does not constitute a disclaimer of that subject matter, as the particular strains and their descendants are included within the scope of the generic claims, for example, generic claims 55-58. Further, Applicants indicated their intention to timely file a continuation application directed to those derivatives and strains to address the § 112 issues in greater detail.

Rejections Under 35 U.S.C. § 112, ¶1

Since issues remained concerning claims 49-53, it was agreed that an additional Office Action would be submitted. Claims 1-5, 9-12 and 49-54 were rejected under 35 U.S.C. §112, first paragraph, for lack of written description. For the reasons discussed below, Applicants respectfully request withdrawal of these rejections.

A.) The Examiner states that step (d) of claim 1, requiring "transferring the separated transferable reproductive elements to secondary cultures," lacks written description. Applicants respectfully traverse this rejection. As discussed above and during the March 15 and 16, 2006 telephonic interviews, Section J of the Examples, titled "Transfer Of Fungal Growth Units" (pp. 56-57), describes transferring reproductive elements from a first culture to a second culture, such as the wells of a microtiter plate. The Examiner indicated during the March 16, 2006 interview that the disclosure of pages 56-57 provides support for this step. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

The Examiner has also rejected claims 49-53 as lacking written description for the phrase "descendants thereof." Applicants traverse this rejection. For example, on page 14 it is disclosed that "strains derived from *Chrysosporium* predecessors including those that have mutated either naturally or by induced mutagenesis" are expressly "included within the definition

Appl. No. 09/834,434

Docket No. 3123-4006

of *Chrysosporium*." One skilled in the art can readily identify suitable descendants (e.g., mutants) based on the disclosure that they tend to produce transferable reproductive elements in suspension, exhibit a compact growth morphology, and a phenotype characterized by submerged growth and reduced viscosity of the fermentation medium when cultured in suspension. The application further teaches that mutants of *Trichoderma*, *Aspergillus sojae*, and *Aspergillus niger* also exhibit similar phenotypes. See p. 14, lines 21-30. Accordingly, one skilled in the art would recognize that Applicants were in possession of embodiments of the method wherein the filamentous fungus is a "descendant" of the named strains and would readily be able to select suitable descendants.

Nonetheless, to expedite allowance of the claims, claims 49-53 are amended herein to delete the phrase "descendants thereof." Applicants will file a continuation application to pursue claim directed to descendants of the recited strains. In view of the deletion of the phrase "descendants thereof," this rejection is rendered moot.

B.) The Examiner has rejected claims 49-53 under §112, first paragraph, for lack of written description. It appears from the Office Action that the Examiner believes that Applicants have failed to comply with the conditions for deposit set forth in 37 C.F.R. §§ 1.806 and 1.808(a). Attached herewith is a "Statement Under 37 C.F.R. §§ 1.806 And 1.808" with respect to *Chrysosporium* strain UV18-25 mutant (VKM F-3631 D) and *Chrysosporium lucknowense* strain C1 (VKM F-3500 D) recited in claims 49 and 50, respectively. As stated in that paper, Applicants agree to comply with all deposit requirements concerning term and access set forth in 37 C.F.R. §§ 1.806 and 1.808. It is believed that a statement under 37 C.F.R. § 1.807 is not required because, as provided in MPEP § 2409, "a mere statement by an applicant, an authorized representative of the applicant or the assignee that the deposit has been accepted under the Budapest Treaty would satisfy 37 CFR 1.807." Because the deposit was made and accepted under the Budapest Treaty, it is believed that 37 C.F.R. § 1.807 is satisfied. Applicants are aware of no other provisions of the C.F.R. which need to be addressed. In view of this statement, Applicants respectfully assert that deposit has been perfected and kindly request withdrawal of the rejection of those claims under §112, first paragraph.

With respect to the fungi *Trichoderma longibrachiatum* strain X-252 (claim 51),

Appl. No. 09/834,434

Docket No. 3123-4006

Aspergillus sojae strain pclA (claim 52) and *Aspergillus niger* strain pclA (claim 53), Applicants respectfully submit that deposit is not required to satisfy §112, first paragraph because the skilled artisan would readily be able to make and identify these strains based on the disclosure in Applicants' specification and the numerous enabling literature references cited therein. For example, Applicants direct the Examiner to Example sections A.(1) "Construction of an *A. niger* proprotein processing unit" (pp. 34-36) and A.(2) "Construction of an *A. sojae* proprotein processing unit" (pp. 36-37). These passages provide detailed explanation of how to make and identify *Aspergillus sojae* strain pclA and *Aspergillus niger* strain pclA based on transformation of readily available fungi using gene replacement and gene disruption vectors. Applicants submit that one skilled in the art would be able to make these strains without undue experimentation based on a reading of the exemplary transformations discussed above and general background and literature references discussed at page 34, line 10 to page 35, line 29. Further, one skilled in the art would readily identify strains identify *Aspergillus sojae* strain pclA and *Aspergillus niger* strain pclA based on southern analysis and the compact growth morphology. In view of these detailed disclosures, Applicants respectfully traverse the rejection of claims 51-53 under §112, first paragraph. Nonetheless, solely to expedite allowance of this application, claims 51-53 will be pursued in a continuation application and are therefore cancelled herein without prejudice.

Rejections Under 35 U.S.C. § 112, ¶ 2

Claims 52 and 53 stand rejected under 35 U.S.C. §112, second paragraph, for being indefinite. Specifically, the Examiner states that it is not clear how the fungi *Aspergillus sojae* strain pclA (claim 52), and *Aspergillus niger* strain pclA (claim 53) are derived from the fungus deposited under accession number ATCC 11906. Applicants respectfully traverse this rejection on the grounds discussed above with regards to §112, first paragraph. Specifically, Applicants submit that Example sections A.(1) "Construction of an *A. niger* proprotein processing unit" (pp. 34-36) and A.(2) "Construction of an *A. sojae* proprotein processing unit" (pp. 36-37) provide detailed explanation of how to make and identify *Aspergillus sojae* strain pclA and *Aspergillus niger* strain pclA. Accordingly, one skilled in the art can readily ascertain the metes and bounds of claims 52 and 53. However, in light of the cancellation of claims 52 and 53, this rejection is now moot.

Appl. No. 09/834,434

Docket No. 3123-4006

CONCLUSION

In view of the foregoing amendments and remarks, and the agreement reached between the Examiner and Applicants' representative on March 16, 2006, May 3, 2006, and May 9, 2006 Applicants respectfully assert that the present case is now in condition for allowance.

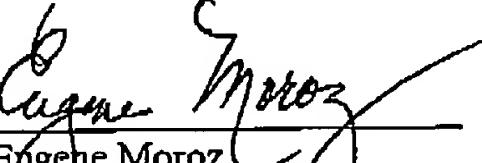
Appl. No. 09/834,434

Docket No. 3123-4006AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 3123-4006. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 3123-4006. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
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Dated: May 10, 2006By: 
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